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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,272	10/17/2001	Michael Rud Lassen	LASSEN=2A	4444

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/978,272

Applicant(s)

Lassen et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/28/02, 3/11/2002, 12/3/2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 24, 42, part (iv), has an “application zone...comprising at least one conjugate....” Is this the same conjugate as in part (iii)? If it is not the same, then what are the characteristics of the conjugate? In addition, part (iv) states that the application zone is in liquid contact with the detection zone. Does that mean that the kit is shipped wet, or does the “liquid contact” refer to something that happens when the kit is used in an assay? Part (vi) says what the positive control zone does, but does not identify what the control zone contains; what are the components present in the positive control zone in the claimed kit? This also affects dependent claims.

In the previous Office action, the meaning of “RS virus related biological cell” was questioned. The response indicates that the intent was “an RS virus infected cell”. This response raises two issues. If the intent is “an infected cell,” and the specification (page 1, lines 5-9 and page 9, lines 4-10) reasonably conveys the concept of detecting an infected cell, then the intended meaning of the claim is confused by using the term “related” instead of the definite “infected.” Second, if claim 1 is directed to a kit for detecting RSV or RSV-infected cells (as indicated by the response), then what is meant by claims 5 and 6? These claims would fail to further limit, since

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“paramyxovirus” in claim 1 is broader in scope than RSV, and RSV in claim 6 is the same scope as RSV in claim 1. Since claims 5 and 6 can be read to indicate that the meaning of “related” is something broader than “infected”, the intended meaning of “related” is still seen as indefinite. This affects claims 1, 24, 42, and dependent claims.

In claim 2, does “the conjugate” refer to the conjugate of claim 1 part (iii) or to the conjugate of part claim 1 (iv)? If part (iii) is intended, the parent claim already requires both a targeting species and a labeling species bound to a polymeric carrier; how does claim 2 further limit? Nothing can be bound without some sort of “connecting moiety”. Is the intent to require the targeting species and/or the labeling species to be connected to the polymer by a linker molecule? If claim 2 is meant to further limit the conjugate of claim 1, part (iii), then the claim would be more clear if it used something other than (i), (ii), and (iii) to list the claim elements.

In claims 7 and 29, how do all of the members of the Markush group of “targeting species” bind an RSV infected cell or an RSV particle? How would antigens, haptens, gene probes, oligonucleotides, polynucleotides, polysaccharides, lectins, avidin, streptavidin, biotin, growth factors, hormones, receptor molecules, protein A, or protein G bind either infected cells or virus? What targeting species are capable of distinguishing an RSV infected cell from an uninfected cell?

Claim 43 is confusing, because parts (i) and (ii) are identical, and parts (i)-(iii) set forth different steps than claim 42; are these intended as additions or substitutions for the steps of claim 42?

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***Claim Rejections - 35 USC § 103***

Claims 1-20, 24, 25, 28-36, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swierkosz et al (Journal of Clinical Microbiology 27:1151-1154, 1989) in view of Tsutsumi et al (Journal of Clinical Microbiology 37:2007-2009, 1999), Ouchi et al (J. Infect. Chemother. 5:230-222, 1999), and Osikowicz et al (US 5,075,078). Swierkosz teaches a fast and convenient enzyme immunoassay kit for direct detection of respiratory syncytial virus (RSV), with a microparticle-conjugated anti-RSV antibody bound to a solid support in a detection zone, and a movable conjugate with anti-RSV antibody conjugated to microparticles and to biotin label. The kit also includes a positive control zone. This differs from the claimed invention in that the kit lacks a separate application zone, and in that the positive control zone is not used to confirm movement of the sample, and in that the reference is silent upon how many particles/microliter are detectable. However, Tsutsumi and Ouchi both teach an immunochromatography kit for direct detection of another respiratory virus. Tsutsumi teaches that the sample is applied in an application zone, migrates to a detection zone, and excess sample migrates past to a positive control zone. The detection zone has anti-viral antibody bound to the solid support, and the mobile phase has anti-viral antibody conjugated to a gold colloid label. Ouchi teaches that the immunochromatography kit is fast and convenient, and more sensitive than enzyme immunoassay kits. Therefore, one of ordinary skill in the art would have had motivation to modify the Swierkosz enzyme immunoassay kit to obtain improved sensitivity of an immunochromatography assay, while retaining advantages of speed and convenience, with reasonable expectation of

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success based upon the results obtained by Tsutsumi and Ouchi for an analogous respiratory virus. Neither Tsutsumi or Ouchi use a polymer-conjugated label for the detection antibody. However, Osikowicz teaches that a variety of different materials are suitable as labels in immunochromatographic method, including polymer-conjugated materials, see for example column 11, line 33 to column 12, line 20. While none of the references measure the sensitivity of detection in the same units used in applicant's claims, all are capable of detecting the amount of virus found in clinical samples, which is the goal of applicant's procedure. Therefore there is reason to believe the method, as suggested by the combined teachings of the references, would achieve the level of sensitivity recited in the claims, even without stating measurements in the same units. For these reasons, the invention as a whole is seen as prima facie obvious, absent unexpected results.

Claims 21-23, 26, 27, 37-41, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swiekosz et al in view of Tsutsumi et al, Ouchi et al, and Osikowicz et al as applied to claims 1-20, 24, 25, 28-36, 42 above, and further in view of Sheeran et al (Pediatric Infectious Disease Journal 18:115-122, 1999, abstract only cited). These claims differ from the above in further requiring detection of an inflammatory indicator, specifically one or more cytokines. Sheeran teaches that certain cytokines are correlated with disease severity in RSV infection. Therefore one of ordinary skill would have been motivated to include means to detect these cytokines in an RSV diagnostic kit and method, for the purpose of indicating disease severity. Therefore the invention as a whole is prima facie obvious, absent unexpected results.

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*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 23, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
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